The listing of claims presented below replaces all prior versions, and listings, of claims in the application.

Listing of the Claims

Claims 1-21 (cancelled).

22. (Withdrawn) A method of treating and/or preventing a bacterial infection disease comprising: administering to a subject in need thereof, a pharmaceutical composition comprising: a pharmaceutically effective amount of benzoquinolizine-2-carboxylic acid antimicrobial drug of the formula (I) according to claim 1; singly or in combination with a pharmaceutically effective amount(s) of a retinoid, an antibacterial, a steroid/non-steroid antiinflammatory agent, an antifungal agent or mixtures thereof.

23. (Withdrawn) The method of claim 22, wherein the benzoquinolizine-2-carboxylic acid antimicrobial drug is RS-(+)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidi-n-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid arginine salt and solvatomorphic or polymorphic forms thereof.

24. (Withdrawn) The method of claim 33, wherein the benzoquinolizine-2-carboxylic acid antimicrobial drug is S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1– yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid arginine salt and solvatomorphic or polymorphic forms thereof.

25. (Withdrawn) The method of claim 33, wherein the benzoquinolizine-2-carboxylic acid antimicrobial drug is S-(-)-9-fluoro-6,7-dihydro-8-(4-

hydroxypiperidin-1- yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid 0.2 hydrate.

26. (Withdrawn) The method of claim 33, wherein the benzoquinolizine-2-carboxylic acid antimicrobial drug is S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-- yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid.

27. (Withdrawn) The method of claim 33, wherein the benzoquinolizine-2-carboxylic acid antimicrobial drug comprises about 0.1-10% by weight of the composition.

28. (Withdrawn) The method of claim 33, wherein the benzoquinolizine-2-carboxylic acid antimicrobial drug comprises about 1% by weight of the composition.

29. (Withdrawn) The method of claim 33, wherein the benzoquinolizine-2-carboxylic acid antimicrobial drug comprises about 0.5% by weight of the composition.

30. (Withdrawn) The method of claim 33, wherein the retinoid comprises adapalene.

31. (Withdrawn) The method of claim 33, wherein said antibacterial is selected from the classes of aminoglycosides, cephalosporins, diaminopyridines, oxazolidinones, sulfonamides, tetracyclines or combinations of these classes.

32. (Withdrawn) The method of claim 33, wherein the steroid comprises clobetasol.

33. (Withdrawn) The method of claim 33, wherein said non-steroid antiinflammatory agent is selected from the group consisting essentially of ibuprofen, indomethacin, ketoprofen, flurbiprofen, celecoxib, valdecoxib, rofecoxib, varecoxib, parecoxib, meloxicam, nimesulide, etodolac, combinations and mixtures thereof.

34. (Withdrawn) The method of claim 33, wherein the antifungal agent comprises butenafine.

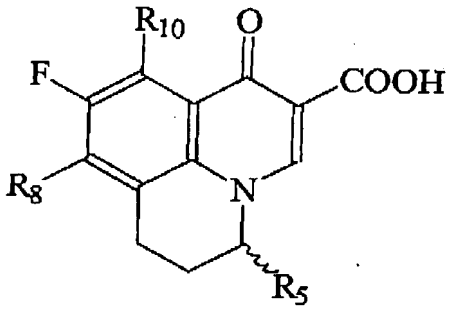
35. (Withdrawn) The method of claim 33, wherein said composition is in a physical form selected from concentrates, drops, pastes, ointments, creams, milks, pomades, powders, impregnated pads, tulles, solutions, gels, sprays, shampoos, lotions, suspensions, microspheres, nanospheres, lipidic vesicles, polymeric vesicles, polymeric patches or biological inserts.

36. (Withdrawn) The method of claim 33, wherein the subject is an animal or human.

37. (Withdrawn) The method of claim 33, wherein the route of administration is selected from ocular, nasal, otic, rectal, vaginal, intradermal, intratumoral, intralesional, intravascular, topical, transdermal, local, regional, or loco-regional.

38. (Currently amended) A stable pharmaceutical composition comprising:

a pharmaceutically effective amount of benzoquinolizine-2-carboxylic acid antimicrobial drug of the formula:

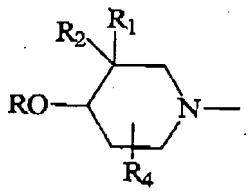


(I)

wherein:

R_5 is CH_3 ~~C_{1-6} alkyl, as a mixture of enantiomers or in a stereochemical orientation~~;

R_8 is



wherein R, R_1, R_2 and R_4 are hydrogen;

R_{10} is hydrogen ~~selected from H, C_{1-5} alkyl, amino, alkylamino and acylamino groups~~;

or an optical isomer, diastereomer or enantiomer thereof, or a polymorph thereof or pharmaceutically acceptable salt or hydrate thereof or mixtures thereof; in combination with a pharmaceutically effective amount(s) of a

retinoid, or a steroid antiinflammatory agent, or a non-steroid, antiinflammatory agent or, or a non-steroid antiinflammatory agent, or an antifungal agent or mixtures thereof.

39. (Currently amended) The composition of ~~claim 1~~ claim 38, wherein the benzoquinolizine-2-carboxylic acid antimicrobial drug is selected from the group consisting of

RS-(±)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid;

R(+)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid;

S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid;

RS-(±)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid arginine salt and solvatomorphic or polymorphic forms thereof;

R(+)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid arginine salt and solvatomorphic or polymorphic forms thereof; and

S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid arginine salt and solvatomorphic or polymorphic forms thereof.

40. (Currently amended) The composition of ~~claim 2~~ claim 39, wherein the benzoquinolizine-2-carboxylic acid antimicrobial drug is S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid arginine salt and solvatomorphic or polymorphic forms thereof.

41. (Currently amended) The composition of ~~claim 2~~ claim 39, wherein thebenzoquinolizine-2-carboxylic acid antimicrobial drug is S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid.

42. (Currently amended) The composition of ~~claim 1~~ claim 38, wherein the benzoquinolizine-2-carboxylic acid antimicrobial drug comprises about 0.1 - 10 % by weight of the composition.

43. (Currently amended) The composition of ~~claim 1~~ claim 38, wherein the benzoquinolizine-2-carboxylic acid antimicrobial drug comprises about 1 % by weight of the composition.

44. (Currently amended) The composition of ~~claim 1~~ claim 38, wherein the benzoquinolizine-2-carboxylic acid antimicrobial drug comprises about 0.5 % by weight of the composition.

45. (Currently amended) The composition of ~~claim 1~~ claim 38, wherein said retinoid is selected from the group consisting of retinoic acid, adaplanene, isotretinoin, motretinide, tretinoin, tazarotene, combinations and mixtures thereof.

46. (Currently amended) The composition of ~~claim 1~~ claim 38, wherein the retinoid is adapalene.

47. (Currently amended) The composition of ~~claim 1~~ claim 38, wherein said steroid is selected from the group consisting of 21-acetoxypregnnolone, alclometasone, algestone, amcinonide, beclomethasone, betamethasone, budesonide, chloroprednisone, ciclesonide, clobetasol, clobetasone, clocortolone, cloprednol, corticosterone, cortisone, cortivazol, deflazacort, desonide, desoximetasone, dexamethasone, diflorasone,

diflucortolone, difluprednate, enoxolone, fluazacort, flucloronide, flumethasone, flunisolide, fluocinolone acetonide, fluocinonide, fluocortin butyl, fluocortolone, fluorometholone, fluperolone acetate, fluprednidene acetate, fluprednidene acetate, fluprednisolone, flurandrenolide, fluticasone propionate, formocortal, halcinonide, halobetasol propionate, halometasone, halopredone acetate, hydrocortamate, hydrocortisone, loteprednol etabonate, mazipredone, medrysone, meprednisone, methylprednisolone, mometasone furoate, paramethasone, prednicarbate, prednisolone, prednisolone 21-diethylaminoacetate, prednisolone sodium phosphate, predisone, prednival, prednylidene, pimexolone, tixocortol, triamcinolone, triamcinoloneacetonide, triamcinolone benetonide, triamcinolone hexacetonide, combinations and mixtures thereof.

48. (Currently amended) The composition of ~~claim 1~~ claim 38, wherein the steroid comprises clobetasol.

49. (Currently amended) The composition of ~~claim 1~~ claim 38, wherein the steroid comprises mometasone.

50. (Currently amended) The composition of ~~claim 1~~ claim 38, wherein said non-steroid antiinflammatory agent is selected from the group consisting of ibuprofen, indomethacin, ketoprofen, flurbiprofen, celecoxib, valdecoxib, rofecoxib, varecoxib, parecoxib, meloxicam, nimesulide, etodolac, combinations and mixtures thereof.

51. (cancel)

52. (Currently amended) The composition of ~~claim 1~~ claim 38, wherein said antifungal agent is selected from the group consisting of amphotericin, nystatin, caspofungin, griseofulvin, oligomycins, butenafine, naftifine, terbinafine, bifonazole, clotrimazole, ketoconazole, miconazole, liranaftate, tolnaftate, fluconazole,

itraconazole, and voriconazole.

53. (Previously Presented) The composition of claim 52, wherein the antifungal agent comprises butenafine.

54. (Currently amended) The composition of ~~claim 1~~ claim 38, wherein the pharmaceutically acceptable vehicle further comprises a pH modifying agent selected from acids, bases, inorganic basic salts, organic basic salts, buffering agents or mixtures thereof.

55. (Currently amended) The composition of ~~claim 1~~ claim 38, that is in a physical form and is selected from the group consisting of drops, pastes, ointments, creams, milks, pomades, powders, impregnated pads, tulles, solutions, gels, shampoos, lotions, suspensions, microspheres, nanospheres, lipidic vesicles, polymeric vesicles, polymeric patches and biological inserts.